Adverse health and ethical impacts of formula

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Disclosure

The speaker(s) have no conflicts of interest to disclose.

Objective

Discuss the adverse health and ethical impacts of marketing formula in the birthing Hospital

The Risks of Formula Feeding

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Faculty Ten Steps to Successful Breastfeeding Collaborative

Health Impacts of Infant Formula

- Risk : Benefit Communication
 - Ongoing reciprocal communication among all interested parties is an integral part of the risk management process. Risk communication is more than the dissemination of information, and a major function is the process by which information and opinion essential to effective risk management is incorporated into the decision.

(Bennett and Calman 1999)

Inform all pregnant women of the benefits and management of breastfeeding

In order to make an informed decision regarding infant feeding women need:

- Information that is accurate
- To understand the information presented
- Confidence in her ability to exclusively breastfeed her baby
- Support to carry out feeding decisions



The Benefits of Breastfeeding

Research shows that breastfeeding gives your baby the best start in life. Here are some of the remarkable benefits of breastfeeding for you and your baby:

Inform all pregnant women of the benefits and management of breastfeeding

Baby

Acute otitis media
Atopic dermatitis
Asthma
Type 1 diabetes
Type 2 diabetes
NEC
Obesity
Lower Respiratory Infections
Sudden Infant Death Syndrome

Mother

Breast cancer
Diabetes type 2
Ovarian cancer
Postpartum depression



Inform all pregnant women of the benefits and management of breastfeeding

- Decreased maximum infant weight loss
- Decreased need for supplementation
- Increased breastmilk intake on day 3
- Onset of lactogenesis II
- Decreased hyperbilirubinemia
 Yamauchi & Yamanouchi. Pediatrics. 1990.
- Stabilizes neonatal glucose levels
 Hawdon et al. Arch Dis Child. 1992.
- Increased rate of weight gain

De Carvalho et al. Pediatrics. 1983.



What about the RISKS of Formula Feeding for infant and maternal health?



Inform all pregnant women of the Risks of Formula Feeding

Baby

Acute otitis media
Atopic dermatitis
Asthma
Type 1 diabetes
Type 2 diabetes
NEC
Obesity
Lower Respiratory Infections
Sudden Infant Death
Syndrome

Mother

Breast cancer
Diabetes type 2
Ovarian cancer
Postpartum depression



Otitis Media

Odds Ratios for Risk of Otitis Media Associated with Any Formula Use

Study Prospective Cohort	N	Duration of Exclusive Breastfeeding	Odds Ratio for Risk with Any Formula Use	p-value
Duffy	238	≥ 3 months	2.70 (1.10, 6.67)	0.030
Scariati	1,410	≥ 6 months	1.78 (1.19, 2.70)	0.005
Duncan	1,013	> 4 months	1.64 (1.08, 2.50)	0.020
Duffy	238	≥ 6 months	4.55 (1.64, 12.50)	0.004
Pooled		≥ 3-6 months	2.00 (1.40, 2.78)	<0.005

Asthma

Odds Ratios for Risk of Asthma with Any Formula Use

Study Prospective Cohort	N	Duration of Exclusive Breastfeedin	Odds Ratio for Risk with Any Formula Use	p-value
Marini et al	359	≥ 4 months	2.00 (1.10, 3.85)	0.02
Wright	1,043	≥ 4 months	0.11 (0.05, 0.29)	< .001
Oddy et al	2,187	> 4 months	1.25 (1.52, 2.02)	0.03
Kull et al	3,384	≥ 4 months	1.72 (1.14, 2.63)	0.01

Diabetes Type I

Odds Ratios for Risk of Type 1 Diabetes with Any Formula Use

Study Case Control	N	Duration of Exclusive Breastfeedin	Odds Ratio for Risk with Any Formula Use	p-value
McKinney et al	195 cases 325 controls	Initial, prior to hospital discharge	1.67 (1.12-2.44)	0.01

Diabetes Type II

Odds Ratios for Risk of Type 2 Diabetes with Any Formula Use

Study Retrospective Cohort	N	Duration of Exclusive Breastfeedin	Odds Ratio for Risk with Any Formula Use	p-value
Petit et al	720	≥ 2 months	2.44 (1.08, 5.56)	0.03

Atopic Dermatitis

Odds Ratios for the Risk of Atopic Dermatitis with Any Formula Use Family History of Atopic Dermatitis

Study	N	Duration of Exclusive Breastfeeding	Odds Ratio for Risk with Any Formula Use	p-value
Berth-Jones et al Prospective Cohort	413	> 4 months	2.27 (1.10-5.00)	0.03
Matthews et al	23 patients 19 controls	> 3 months	5.88 (1.11–33.33)	0.04

Hospitalization Secondary to Lower Respiratory Infection

Study	N	Duration of Exclusive Breastfeeding	Odds Ratio for Risk with Any Formula Use	p-value
Bacharach et al Meta-analysis 7 observational studies	3,201 BF 1,324 NBF	> 2 months (includes some who were BF > 9 months, not EBF)	3.57 (1.85, 7.14)	<0.001
Quigley et al Longitudinal cohort	15,890	> 4 months	1.52 (1.09, 2.13)	0.01

Odds Ratios for the Risk of Hospitalization Secondary to Lower Respiratory Tract Diseases (LRTI) Associated with Any Formula Use

Necrotizing Enterocolitis

- Formula fed Premature Infants <33 weeks gestation are 10 times more likely to develop NEC
- Formula + Breastmilk fed Premature infants are 3 times more likely to develop NEC
- Damaging bile acids are higher in the guts of premature infants who are fed formula
- Formula contains No immunologic protection
- Formula contains No Epidermal Growth Factors
- Pasteurized Donor Milk is next best~ (7 RCTs, n = 471) that DM decreased an infant's risk for NEC by nearly 80% compared with formula (RR = 0.21, 95% CI: 0.06-0.76)

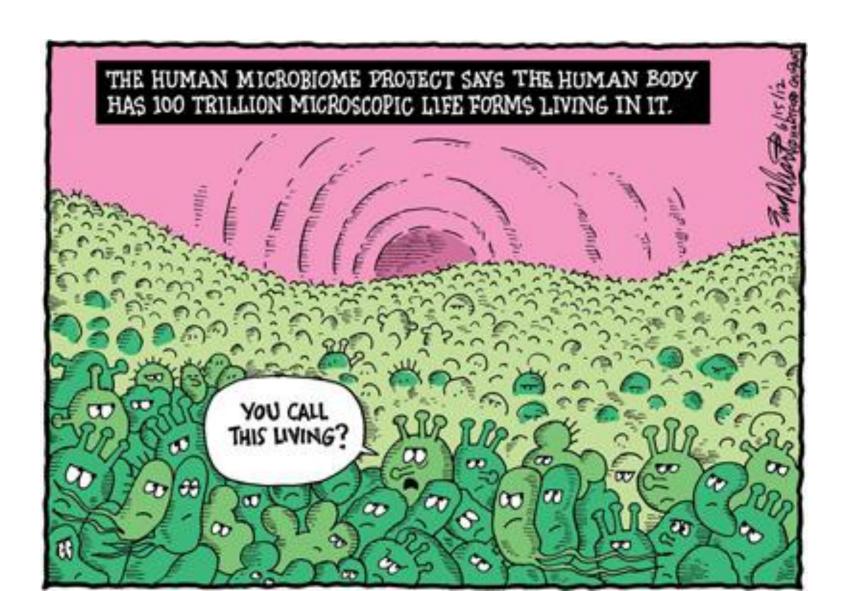
Sudden Infant Death Syndrome

Study	N	Duration of Breastfeeding	Odds Ratio	<i>P-</i> value
Hauke Pediatrics 2003	260 cases 260 controls	ever	0.4 (0.2, 0.7)	
Chen Pediatrics 2004	1204 cases 7740 controls	ever	0.84 (0.67, 1.05)	
Venneman Pediatrics 2009	333 cases 998 controls	Exclusive	0.27 (0.13, 0.16)	<.001
Venneman	333 cases 998 controls	Mixed	0.29 (0.16, 0.53)	<.001

Why is breastmilk so protective of disease?

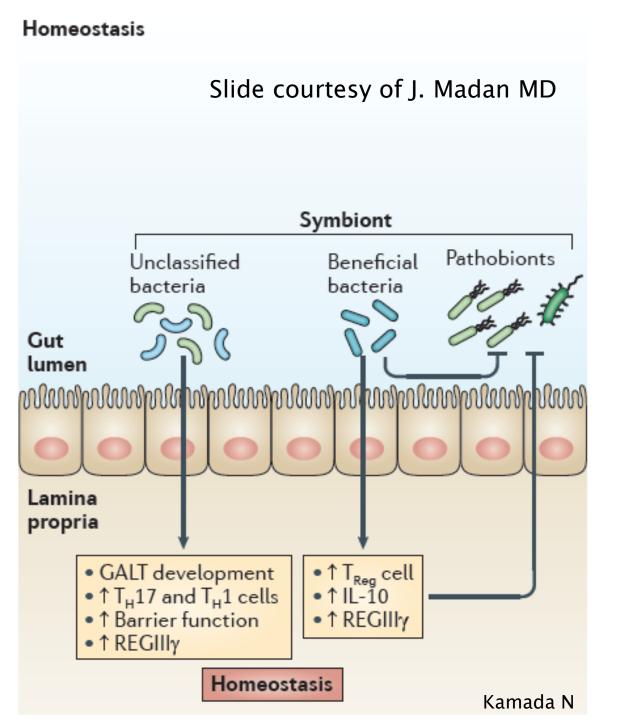
Emerging evidence reveals the interplay between the human genome and microbiome may hold the key to current and future health

Human Microbiome



Microbiata: The human microbiota consists of the 10-100 trillion symbiotic microbial cells harbored by each person





Although hostassociated microbes are presumably acquired from the environment, the composition of the mammalian microbiota, especially in the gut, is surprisingly different from free-living microbial communities. 3.3 million nonredundant genes in the human gut microbiome alone as compared to the \sim 22,000 genes present in the entire human genome.

Dr. Juliette Madan's Work!







Early life and the critical window for immune programming



 Innate and adaptive immunity evolved to require microbial interactions during development

Lee YK et al. Science 2010, Chow J et al Adv Immunol 2010

- TLR, Class I & II MHC, CD4 T, GALT
- Early life colonization critical to fine-tuned immune homeostasis Hansen C et al Gut Microbes 2013
- Certain exposures may have profound effects on the microbiome in early life
 - ?Affecting disease risk for a lifetime

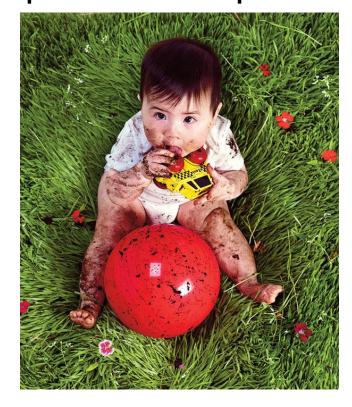
The microbiome is dynamic: the exposome

Beginning at birth, multiple exposures shape

the microbiome

Relatively stable by age 3

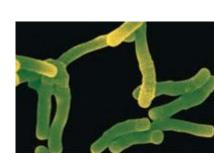
- Exposures thought to be important:
 - Delivery mode
 - Infant diet
 - Hospitalizations
 - Antibiotics



Many of these exposures can be altered

Specific microbes and immunity

- Bifidobacterium associated with enhanced maturation of mucosal immunoglobulins
- Early colonization with *B. fragilis* associated with decreased immune responsiveness
- Decreased gut microbial diversity associated with early onset allergy
- Specific microbes associated with allergy
 - ↑ Clostridia or ↓ Bifidobacteria



Our questions

- Is the neonatal period a critical window for a lifetime of health programming?
- Are there patterns in early life microbiome that can:
 - predict disease risk
 - predict disease progression
 - or be altered?

Dr. Madan and Research Team

Previous microbiome work

RESEARCH ARTICLE



Serial Analysis of the Gut and Respiratory Microbiome in Cystic Fibrosis in Infancy: Interaction between Intestinal and Respiratory Tracts and Impact of Nutritional Exposures

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School of Medicine, Hampshire, USAe; Jo Medicine at Dartmo Dartmouth, Lebano Idaho, USAi; and Div

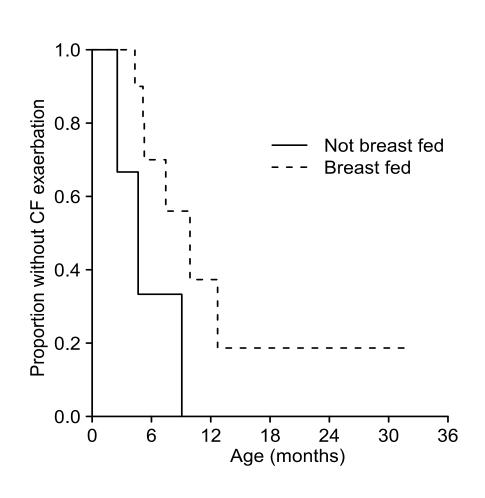
The Journal of Pediatrics • www.jpeds.com

ORIGINAL ARTICLES

Associations between Gut Microbial Colonization in Early Life and Respiratory Outcomes in Cystic Fibrosis

Anne G. Hoen, PhD^{1,2,*}, Jing Li, MS^{1,*}, Lisa A. Moulton, RN³, George A. O'Toole, PhD⁴, Molly L. Housman, MS⁴, Devin C. Koestler, PhD⁵, Margaret F. Guill, MD³, Jason H. Moore, PhD¹, Patricia L. Hibberd, MD, PhD⁶, Hilary G. Morrison, PhD⁷, Mitchell L. Sogin, PhD⁷, Margaret R. Karagas, PhD², and Juliette C. Madan, MD, MS⁸

Breastmilk exposure associated with longer time to first CF exacerbation



Summary

- Nutritional factors are determinants of bacteriology and diversity in both systems
- Respiratory outcomes strongly correlated with breast feeding
- Specific bacterial communities in the gut prior to respiratory complications in CF highlight a connection between intestinal microbiome and systemic health
- Presenting opportunities for intervention?

Breastfeeding & Diet

- Feeding type influences microbiome composition directly
 - Substrates and bacteria Le Heurou-Luron Nutr Res 2010
- Breast milk presents a complex composition
 - Growth factors, cytokines, immunoglobulins, enzymes, oligosaccharides
- Oligosaccharides in breastmilk:
 - Promote Bifidobacterium growth in the gut Zivkovik AM et al PNAS 2011
 - Lactobacillus, Bacteroides and Enterobacteria



Breastfeeding & Diet

- Breastfed newborns have a more stable and uniform population compared with formula fed Bezirtzoglou E Anaerobe 2011
- Relatively small amounts of formula supplementation of breast fed infants result in shifts to a formula fed pattern Mackie RI Am J Clin Nutr 1999

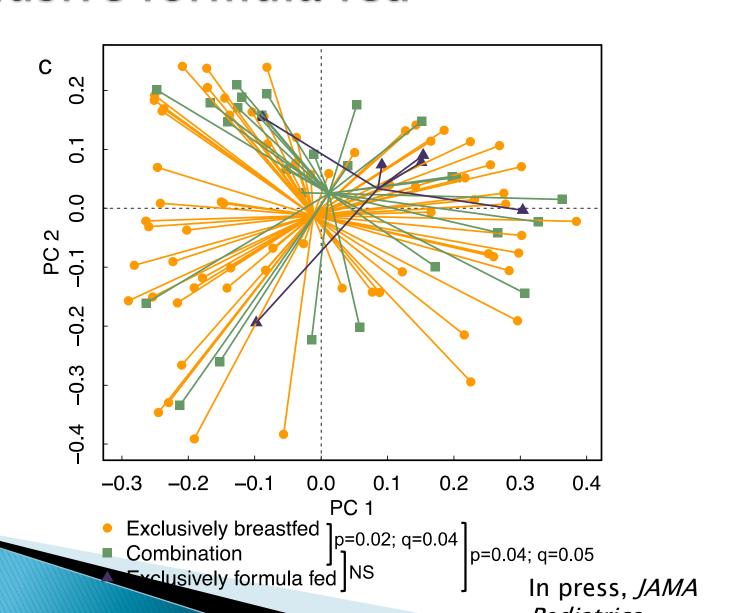
Formula & Diet

- Infants fed formula have higher proportions of
 - Bacteroides
 - Streptococcus
 - Enterococcus
 - Prevotella Holscher et al JPEN J Parenter Enter Nutr 2012
 - Clostridia difficile (associated with eczema)
- Transition from:
 - breast milk to formula,
 - introducing solid foods,

profoundly influence the bacterial succession

Fallani et al Microbiol 2011

Combination fed more similar to exclusive formula fed



Future research & clinical implications

- Potential translation to clinical work:
 - Breast milk benefits
 - Limiting or altering antibiotic exposure
 - Targeted probiotics
 - Individualization of medication regimens based on microbe profiles
 - Predicting disease risk based on microbe profiles

Risk Communication

- Guilt
- Trauma
- Sadness
- Lack of Information
- Lack of Support



- Can be mediated/prevented
 - Effective communication
 - Evidence based breastfeeding management
 - Relationship development
 - Close and frequent lactation follow up/visits

The more you know about the past, the better prepared you are for the future.

Theodore Roosevelt

Importance of Infant Formula

- Strict Contraindications to breastfeeding:
 - HIV/AIDS in the US
 - Galactosemia
 - chemo

- Relative contraindications
 - Some medicines, Illicit drugs

Formula was invented to save babies from death

- The original intent was to provide babies a safe alternative
- Listed as one of the Top Ten Achievements of Public Health at the CDC, Maternal Child Health, efforts for safe alternatives to breast milk were integral to saving lives particularly from 1900–1930.

Origins of "Baby-Milk" Manufacturing

Response to unhygienic conditions





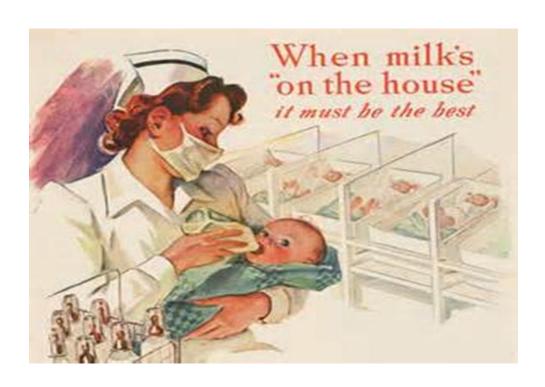
Medicalization of Infant Formula

- Culmination of Mechanistic and Industrial Revolutions and deemed "progress"
- Claims of companies that products were "indispensable to the diet of infants"
- Physicians used as references and part owners in formula companies

A Relationship is Born

- Consensus developed that infant feeding without medical advice was dangerous
- Mead Johnson boasted that their "ethical" marketing policy "was responsible for the advancement of the profession of pediatrics in this country because it brought control of infant feeding under the direction of the medical profession." (Baumslag, 1996).

Advertising Influences Perceptions







Loss of Breastfeeding as Norm

- by 1967 only 25% of discharged newborns were breastfed (Palmer, 2009).
- Formula-feeding seen as symbol of modernity and wealth- still occurs today with some immigrant populations
- No restriction of advertising claims

Nestle Boycott and Aggressive Marketing

- Early efforts of formula manufacturing sought to save infant lives
- 1970's aggressive formula marketing in developing countries caused infant deaths
- Borden, Abbott, and Bristol Myers ceased practices but Nestle continued
- ▶ 1977 Nestle continued, resulting in boycott



WHO Code of Marketing

Health and Safety is the primary concern of the Code



WHO Code of Marketing

- Adopted in 1981 with United States the only country to vote against it
- Later signed by President Clinton, but not backed up with legislation
- Regulated marketing of infant formula and expressly prohibits free formula and any formula marketing in connection with healthcare

Specifics of the Code:

- No free stuff to ANYONE
- No marketing of formula to mothers
- No samples, logos, sales, promotions, coupons, discount programs
- No "donations" unless carefully considered

Order total:	\$0.00
Estimated tax to be collected:	\$0.00
Total before tax:	\$0.00
Free Sample Box:	-\$17.99
Shipping & handling:	\$0.00
Items:	\$17.99
Order Summary	



Timeline Direct-to-Consumer Marketing

- ▶ 1988 Direct-to-consumer marketing of infant formula
- 1990- AAP opposed this citing that it affected breastfeeding negatively, confused consumers, and raised costs

1997-DTC marketing of pharmaceuticals

What's with the tub?



Implications of DTC Marketing

- Higher product costs
- Confusion and Misleading statements
- Some note positives such as less paternalism in health care; pt.

involvement



PhRMA Code of Marketing for Healthcare Professionals



Inform healthcare professional about the benefits and risks of our products to help advance appropriate patient use.

Promotional Materials Guidelines

- Promotional materials provided to healthcare professionals by or on behalf of a company should:
 - (a) be accurate and not misleading;
 - (b) make claims about a product only when properly substantiated;
 - (c) reflect the balance between risks and benefits; and
 - (d) be consistent with all other Food and Drug Administration (FDA) requirements governing such communications

PhRMA Code

The Code expressly prohibits the "giving of any subsidy as an equivalent of a cash gift" non-educational materials such as pens, mugs, post-its, or drug-logo items should not be offered to providers or their staff, even if they are accompanied by educational materials



Parent Companies

- 2013 Abbott splits, gets AbbVie the drug side of business
- Protects stable formula side of business from riskier R & D for pharmaceuticals









Parent Companies





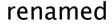


Tales of Acquisitions













2012







Disclaimer on Wyeth Nutrition

- This website is not intended for consumers in the following countries: USA, Canada, Japan, India, Central and South America, Australia, Botswana, Lesotho, Namibia, Swaziland, South Africa and Zambia.
- Breastfeeding is best for babies. The World Health Organization (WHO) recommends exclusive breastfeeding for six months. Wyeth Nutrition fully supports the WHO recommendation and continued breastfeeding, along with the introduction of complementary food as advised by healthcare professionals.



Pfizer, Bristol-Myers Squibb, and Abb-Vie are signatories on PhRMA's Code of Interactions with Healthcare Professionals

Corporate Compliance

- An organization's code(s) of conduct, policies, and procedures designed to achieve compliance with applicable legal regulations and internal ethical standards
- Compliance has changed from an informal reactive posture to one that is structured, proactive, and centralized within the business itself.

Ethics of Healthcare Business Interactions

- Much of corporate compliance programs focus on the legality of business practices such as anti-trust and fraud concerns, but the ethics of business practices are also a consideration for compliance.
- Pharmaceuticals have been primary target for corporate compliance programs.



Office of Inspector General of DHHS

Has called for:

- Reduction in fraud and abuse, improving quality, and reducing costs of health care
- Development of Corporate Compliance programs to show to the public a "commitment to honest and responsible corporate conduct"





Related but Separate

Formula marketing through company bags and discharge packs addressed by Ban the Bag efforts

Free formula given to hospitals

Quest for Global Market-Share

"Overall market for baby food and pediatric nutrition from \$41 billion in 2012 to \$64 billion in 2017" (Campbell, 2015).

China is industry's largest market and

growing



Foundations of Evidence

1992 Study looked at mothers receipt of discharge pack of formula and EBF rates at 1 and 3 weeks of age.

No statistical difference at one week in EBF rates, but at 3 weeks there was a significant decline in EBF (p=<.004).

"Association of Health Profession and Direct-to-Consumer Marketing with Infant Formula Choice and Switching"

Methods: Study of 1700 mothers from (IFPII) were asked about media exposure to formula information during pregnancy, receiving formula samples or coupons at hospital discharge, reasons for their formula choice at infant age 1 month, and formula switching at infant ages 2, 5, 7, and 9 months (Huang, 2013).

"Association of Health Profession and Direct-to-Consumer Marketing with Infant Formula Choice and Switching" (cont.d)

Results:

- Most mothers received both DTC formula marketing and hospital formula samples.
- Mothers who chose formula at one 1 month because their doctor recommended it were less likely to switch formula than those who chose in response to DTC marketing.
- Mothers who chose formula because it was used in the hospital were less likely to switch if they had NOT been exposed to internet ads while pregnant or if they received a sample in the mail.

"Association of Health Profession and Direct-to-Consumer Marketing with Infant Formula Choice and Switching" (cont.d)

Conclusion: Marketing formula through health professionals may decrease mothers' willingness to switch formula.

"The Association of Prenatal Media Marketing Exposure Recall with Breastfeeding Intentions, Initiation and Duration"

Methods: Data were from the (IFPSII). Sample sizes ranged from 1384 to 2530. Looked at associations between recalled prenatal exposure to formula or breastfeeding information and breastfeeding intentions and behavior.

Results: Exposure to infant formula information from print media was associated with shorter intended duration of exclusive breastfeeding, and formula information from websites was related to lower odds of both intended and actual initiation. (Zhang, 2013)

"The Association of Prenatal Media Marketing Exposure Recall with Breastfeeding Intentions, Initiation and Duration" (cont'd.)

CONCLUSION: Mothers who recall exposure to formula information from print or websites are more likely to intend to use formula or to intend to use formula earlier and are less likely to initiate breastfeeding than mothers who do not recall seeing such information.

Removal of Industry-Sponsored Formula Sample Packs from the Hospital: Does It Make a Difference?

Feldman-Winter looked at whether or not switching from formula company bags/discharge packs to hospital-logo diaper bags WITHOUT formula or forms of formula marketing affected BF rates.

Contaminated Study

- 36% mothers in intervention group reported receiving formula!
- Removal of industry-sponsored formula sample packs from an urban hospital was associated with increased breastfeeding over 10 weeks; it was not associated with increased exclusive breastfeeding.

**Illustrates need for staff education

Hospital Formula Discharge Packs

PEDIATRICS

The percentage of hospitals distributing infant formula discharge packs to breastfeeding mothers was 72.6% in 2007 and 31.6% in 2013, a decrease of **41 percentage points**.

Discharge pack use is declining

- 2007 only 1 state (RI) had <25% hospitals distributing discharge packs of formula
- 2013 there were 24 such states and territories.
- Distribution decreased among all types of facilities





Ethical Guidelines

Promotional items are inappropriate in a medical environment and should not be used as patient education materials.

Formula representatives are vendors. They should not be treated as part of the healthcare team. They have succeeded in getting hospital staff to market for them.

Hospital staff and health care providers should not be acting as formula marketers, nor should they lend their prestige to a product that undermines the health of our nation's infants and mothers.

- Started in 2006 in Massachusetts
- Currently 992 US hospitals have banned the bag
- Locations that have banned the bag:
 - Rhode Island
 - Massachusetts
 - Wash., DC
 - Delaware
 - Maryland
 - New York City hospitals
 - Philadelphia





Maine Hospitals that have banned the Bag

- Bridgton Hospital*, Bridgton
- 2. Central Maine Medical Center*, Lewiston
- 3. Eastern Maine Medical Center, Bangor
- 4. Franklin Memorial Hospital, Farmington
- 5. Lincoln County Healthcare*, Damariscotta
- Maine General Hospital of Augusta*
- Maine General Hospital of Waterville
- 8. Miles Memorial Hospital Damariscotta
- Stephens Memorial Hospital*, Norway
- 10. York Hospital*, Portsmouth

*denotes BFHI designated



DO WHAT YOU CAN, WITH WHAT YOU HAVE, WHERE YOU ARE.



- THEODORE ROOSEVELT

Summary

Even without evidence supporting reduced breastfeeding rates, formula marketing has no place in health care settings.

It is unethical to market an inferior product that goes against all recommendations for optimal health outcomes for all populations.

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